REMARKS

The drawings were objected to by reason of certain informalities: the training electrode reference number 200 was missing from Fig. 2; the second layer reference number 510 was missing from Figs. 5 and 6; electrode attachment region reference numeral 506 was missing from Fig. 6; and reference number 514 for the fourth layer in Fig. 8 was missing. These deficiencies have been corrected in the enclosed Replacement Sheet drawings. The objection regarding the child's torso in Fig. 7 has been addressed by editing the text of the paragraph beginning on page 12, line 12.

Objection was made to Fig. 4 as being incomplete. This application is a national stage filing of a PCT application which must meet the drawing requirements of 37 CFR 1.437, which references PCT Article 7 and PCT Rule 11. Section 11.11 of Rule 11 states that text is not to be included in PCT application drawings except for single words or symbols. This is due to translation problems in the many countries with different languages where the international application may be filed. Accordingly, it is respectfully submitted that the "empty box" drawings of Fig. 4 are in compliance with the rules and acceptable. However, the applicants' attorney feels as the Examiner does, that these empty boxes leave much to be desired. Accordingly, an amended Fig. 4 with text is enclosed. The text in the boxes is that which is found in Fig. 4 of the priority provisional application.

It is respectfully requested that the Examiner approve entry of the enclosed three sheets of Replacement Sheet drawings.

Objection was made to certain informalities in the paragraph on page 12 of the specification mentioned above. These informalities have been corrected, as have the corresponding drawings as described above. It is respectfully submitted that the reference to the "second layer 510" on page 12, line 15 is correct, as the first layer 502 is the transparent layer which covers the layer with the electrode placement drawings on them. It is respectfully submitted that these informalities have been resolved.

Claims 4-7 and 13-14 were rejected under 35 U.S.C. §112. Specifically, certain terms in Claims 4 and 7 were cited as lacking antecedent basis. These claims have been amended to overcome this problem. Claim 13 was cited as inconsistently distinguishing between the therapy and training modes. This claim has been amended to more clearly distinguish the two modes and their subjects. Accordingly it is respectfully submitted that Claims 4-7 and 13-14 are now in compliance with Section 112.

Claims 1-6 and 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over US patent pub. 2003/0233129 (Matos) in view of US patent pub. 2003/0199929 (Snyder et al.) Claim 1 describes an external defibrillator selectably usable in one of a therapy mode and a training mode, when in the training mode, having a plurality of training state notifications, and adapted for electrical coupling with an electrode arrangeable on a release liner, the electrode electrically conductive and configured for placement on a subject, comprising an energy source; an electrode interface responsive to the electrode; an energy delivery system operable to selectively deliver electrical energy from the energy source to the electrode via the electrode interface; a state identifier, identifying, when the electrode is electrically coupled to the electrode interface, a degree of electrical connectivity along an electrical path including the electrode; a controller, operative in the training mode, prior to placement of the electrode on the subject, to advance the external defibrillator from a first training state to a second training state when the state identifier identifies a predetermined degree of electrical conductivity along the electrical path; and a user interface, operative in the training mode to issue a training state notification indicating that the external defibrillator has advanced from the first training state to the second training state. An implementation of Claim 1 provides an external defibrillator which can be used to save victims of sudden cardiac arrest and other arrhythmias, and can also be used to train prospective rescuers. The external defibrillator does so by sensing electrical connectivity of an electrode during training. The defibrillator advances a training state when the defibrillator identifies a predetermined degree of conductivity of the electrode's electrical path, and notifies the trainee of the training state advancement. The defibrillator is thus able to teach one of the most important parts of a rescue, the proper handling and application of the electrodes to attach them to the victim securely and in the proper position. Many layperson rescuers, in the excitement of a rescue, do not realize that the electrodes have to be removed from the release liners. By monitoring the conductivity of pre-connected electrodes the defibrillator is able to sense that the release liners have been properly removed. An external defibrillator can sense the handling of pre-connected electrodes by sensing the conductivity change when one electrode is removed from a release liner and its electrical connection to another electrode is broken. When these actions are done properly the defibrillator notifies the trainee of successful completion of these actions by advancing the training. Such notifications are not done in the actual rescue use of the defibrillator, as experience and studies have shown that in the stress of a rescue layperson rescuers become confused and disoriented by excessive lights and sounds from a defibrillator, particularly during the critical

steps of electrode unpackaging and attachment. When these activities are performed correctly during a rescue, the standard practice is for the defibrillator to be quiet and unobtrusive. But in the training mode an implementation of the present invention provides notification to reinforce the success of the correct actions taken by the student.

Matos describes a defibrillator which is intended to be successfully used in a rescue by nonmedical rescuers with no defibrillator training whatsoever, so-called "untrained enablers." It does this by providing a transmitting/receiving device which sends patient bodily function information like the ECG to a central station and provides two-way voice, text, and video communication between the untrained enabler at the rescue scene and a medical professional at the central station. The medical professional is thus able to conduct a remote rescuer by seeing the ECG waveform at the central station as if she were at the rescue, viewing the patient with the video link, and guiding the enabler with voice communication during every step of the rescue. Thus, the enabler is no more than "a pair of hands" at the site of the rescue, guided entirely by the remote medical professional in communication with the enabler at the scene. This is not a training mode, but the therapy mode of the defibrillator. No training mode is shown or suggested by Matos. Indeed, training is not necessary with his defibrillator and, to the contrary, his defibrillator is intended to be used by any individual with no defibrillator experience at all, through direction from the remote medical professional.

The Examiner refers to steps in the rescue flowcharts of Figs. 18E and 18F as being training states, but they are not. These are activities done during an actual rescue. The impedance measurements referenced in step 890 are the chest impedance measurements done after the electrodes are attached to the patient. If the remote medical professional sees no impedance measurement at her central station, she has the enabler do what she would do if she were at the site, which is to check that the electrodes are properly attached to the patient and securely plugged into the defibrillator. She does this by observing the patient over her video link, and questioning the enabler. Unlike Claim 1 of the present application, these are manual activities performed by the enabler under guidance from the medical professional, they are not actions performed by an external defibrillator. They are not done prior to electrode attachment as recited in Claim 1. They are not done during a training mode, as Matos describes no training mode. There is no advancement of a training mode state. There are no notifications by the defibrillator that a training mode state is being advanced.

Snyder et al. was cited for its teaching in paragraph 0009 that it is known to have electrodes with release liners. Snyder et al. also do not show or suggest a training mode.

Snyder et al. provide none of the deficiencies of Matos listed above with respect to Claim 1. Accordingly it is respectfully submitted that the combination of Matos and Snyder et al. cannot render Claim 1 and its dependent Claims 2-14 unpatentable.

Claim 15 describes a method for training a user to operate an external defibrillator, comprising providing an external defibrillator selectably usable in one of a therapy mode and a training mode, the external defibrillator comprising an energy source; an electrode interface responsive to an electrode, the electrode arrangeable on a release liner and configured for placement on a subject; and an energy delivery system operable to selectively deliver electrical energy from the energy source to the electrode via the electrode interface; when the electrode is coupled to the electrode interface, receiving an input signal from the electrode, prior to placement of the electrode on the subject; based on the input signal, identifying a degree of electrical connectivity along an electrical path including the electrode; based on the determined degree of electrical conductivity, advancing the external defibrillator from a first training state to a second training state and issuing a training state notification indicating advancement from the first training state to the second training state. As previously mentioned, neither Matos nor Snyder et al. show or suggest a defibrillator with both a therapy mode and a training mode. To the contrary, Matos' central thesis is that no training is required because any individual can be guided through a rescue by a remote medical professional in data, radio, and video contact with the rescue scene. The steps in Matos are those manually carried out by a medical professional in communication with an enabler at the rescue site, not actions of a defibrillator. There is no advancement of the training states of a defibrillator based on a degree of electrical conductivity along an electrical path including the electrode. There is no issuance of a training state notification in either Matos or Snyder et al. For all these reasons it is respectfully submitted that these patent applications cannot render Claim 15 unpatentable.

Claims 7-14, which depend from Claim 1, were rejected under 35 U.S.C. §103(a) as being unpatentable over Matos and Snyder et al. in view of US Pat. 5,275,572 (Ungs et al.) Ungs et al. describe a pair of training electrode which can be placed on a CPR mannequin during training. An ECK simulator is connected to the training electrodes so that the defibrillator connected to the electrodes will see an ECK signal produced by the simulator. The defibrillator delivers a shock which is dissipated by the EKG simulator. The training electrodes can be covered with their release liner after use so they can be used again, and when their adhesive wears out the training electrodes can be disconnected from their cable and replaced with fresh electrodes. Use of the training electrodes is described in column 4,

lines 59-67. It is seen that the EKG signals are not monitored until after the electrodes are attached to the CPR mannequin. There is no monitoring or detection of any training state change by the defibrillator prior to placement of the electrodes on a subject as called for by Claim 1. The defibrillator in Ungs et al. appears to have no training mode. The description of its use is that it operates during training exactly as it does in a real rescue, including delivers of a therapy shock to the EKG simulator. Generally, training defibrillators or defibrillators with a training mode avoid producing a shock when the shock button is pressed, as the shock is unnecessary, depletes the battery, and endangers the trainee with its high voltage. Like Matos and Snyder et al., there is no suggestion that the defibrillator in Ungs et al. either advances training states or issues any training state notification. The "test" referred to in paragraph 0038 of Snyder et al. is the normal self-test performed by a defibrillator with pre-connected electrodes at power-up. If the impedance of the electrodes measures too high, it means that the electrode gel has dried out and the electrodes are unsuitable for a rescue and must be replaced. This is not a part of any training mode, but part of the normal defibrillator self-test. Thus, it is respectfully submitted that Ungs et al. fail to supply any of the deficiencies with regard to Claim 1 that Matos and Snyder et al. exhibit. Accordingly it is respectfully submitted that Claim 1 and its dependent Claims 7-14 are patentable over Matos, Snyder et al. and Ungs et al.

Claims 16-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Matos in view of Ungs et al. Amended Claim 16 describes a method for performing defibrillator training comprising the steps of providing an automatic external defibrillator training device; providing a pair of training electrodes in electrical communication with said training device; sensing an impedance change between said pair of training electrodes; and advancing a training rescue based on said sensed impedance change. By this method the defibrillator senses an impedance change indicative of proper handling of the electrodes such as removing pre-connected electrodes from a release liner or placement on a training device and advances the rescue training when it senses this impedance change. As previously stated, Matos has no training mode or capability; to the contrary, the Matos system avoids the need for training by having a rescue directed by a remote medical professional. Ungs et al. detect no impedance change, but only a simulated EKG signal when the EKG simulator is turned on. The defibrillator in Ungs et al. will see the simulated EKG signal when the simulator is turned on, and will not see it if the simulator is turned off. Placement of the training electrodes on the mannequin is irrelevant to the reception of the signal and there is no sensing of an impedance change between a pair of training electrodes in either Matos or

Ungs et al. Neither patent is concerned with sensing the handling of electrodes during rescue training. Accordingly it is respectfully submitted that Claim 16 and its dependent Claims 17 and 18 are patentable over Matos and Ungs et al.

In view of the foregoing amendments and remarks it is respectfully submitted that the replacement sheet drawings overcome the drawing objections, the specification now clearly describes the illustrated embodiments of the invention, Claims 4-7 and 13-14 are now clear and definite, and that Claims 1-18 are patentable over the combination of Matos, Snyder et al., and Ungs et al. Accordingly it is respectfully requested that the rejection of Claims 4-7 and 13-14 under 35 U.S.C. §112 and of Claims 1-18 under 35 U.S.C. §103(a) be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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